

REMARKS

Reconsideration of this application as amended is respectfully requested. Claims 1-4, 6-8 and 10-12 have been amended, and claims 5, 9, 13-16, 18, 19, and 21-23 were previously canceled. Accordingly, claims 1-4, 6-8, 10-12, 17, 20 and 24-25 remain in this application and are again presented for the Examiner's consideration in view of the following comments.

In the Official Action, the Examiner objected to the drawings as including reference numerals 22' and 24' which were not mentioned in the description. Applicant has amended the description to refer to thrombectomy wire 22' having a J-shaped tip 24'. Accordingly, applicant submits that the revised drawings now comport with the requirements of U.S. practice.

The Examiner also objected to the specification as missing a word after "another" in the Brief Description of the Drawings for Figure 4. Applicant has amended the description at page 4, line 7 to change the word "from" to --form--. Applicant submits that this amendment corrects a typographical error and overcomes the Examiner's objection.

In addition, the Examiner objected to the specification as failing to provide proper antecedent basis for the use of the word "guide wire" in the claims. Applicant has amended the specification at page 6, third full paragraph, to now refer to "a guide wire or rotatable thrombectomy wire 22." Support for this amendment can be found in the application as filed on page 2, lines 16-22, and at page 8, lines 7-10. Applicant submits that this amendment to the specification overcomes the Examiner's objections thereto.

Claims 1-4, 6-8, 10-12, 17, 20, 24, and 25 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,056,721 to Shulze ("Shulze") in view of U.S.

Patent No. 6,183,487 to Barry et al. ("Barry"). Applicant respectfully traverses this rejection.

Shulze is directed to a combination angioplasty and drug delivery catheter. The catheter includes a series of four axially extending lumens, one lumen being connected to an infusion port for dispensing a therapeutic agent or drug in the blood vessel, another lumen being connected to a high compliance balloon positioned proximally of the infusion port and supplying a fluid or gas for inflating and deflating the high compliance balloon, and a third lumen being connected to a low compliance angioplasty balloon positioned distally of the infusion port and supplying a second fluid for inflating and deflating the low compliance balloon. The fourth lumen in the catheter is for a guidewire as well as the passage of a body fluid or contrast solution from or into the vascular passageway. According to the patentee, "By using a catheter body having a plurality of interior lumens, each having a specific cross-sectional shape and orientation relative to the other lumens, the outer diameter of the catheter body is minimized while fluid flow through the lumens is maximized." (column 2, line 65 through column 3, line 2) Thus, the purpose of Shulze is to provide angioplasty type catheters capable of simultaneous drug delivery in which the catheters are small enough in diameter as to be able to be inserted into narrow, occluded passages.

As noted by the Examiner in the Official Action, Shulze fails to disclose a rotatable guidewire for performing mechanical thrombectomy as required by the claims herein. In order to overcome this deficiency, the Examiner has attempted to combine Shulze with Barry. Barry, however, is plainly incapable of overcoming this deficiency. In that regard, Barry teaches an atherectomy device for removing unwanted deposits from a vessel wall. The device includes a flexible drive shaft having an ablation burr on the end thereof. In each of the embodiments

disclosed therein, the burr has a relatively large diameter so as to contact and ablate the material deposited in the vessel. In the specific embodiment referred to by the Examiner (i.e., Figs. 16-17), a guidewire may extend through the burr and have an abrasive tip on the distal end thereof. The guidewire may spin with the burr or independently thereof so as to ablate deposits in the vessel and create a passageway for the burr. (column 11, line 62 through column 12, line 18)

In view of the stark differences between the drug dispensing catheter of Schulze and the ablation burr of Barry, applicant submits that their combination is inappropriate. An obviousness rejection cannot be made simply by combining references without some teaching or suggestion in those references to make the combination. See *In re Gordon*, 733 F. 2d 900, 22 USPQ 1125 (Fed. Cir. 1984). As stated in *In re Oetiker*, 977 F.2d 1443, 1447, 24 USPQ 2d 1443 (Fed. Cir. 1992):

There must be reason, suggestion or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make that combination. That knowledge cannot come from the applicant's invention itself.

The Examiner has contended that it would be obvious to one of ordinary skill in the art to incorporate the guidewire of Barry into the device of Shulze so as to remove material from a stenosed vessel by a mechanical alternative such as a rotatable wire. Applicant respectfully disagrees.

As noted above, the device of Shulze is for depositing a drug at a point of vessel occlusion. As specifically noted by Shulze, "These drugs are typically used to soften, dissolve or even prevent the reoccurrence of the obstruction". (column 1, lines 25-27) Therefore, one of skill in the art would not be motivated to replace the drug of Shulze with a mechanical

ablation device because to do so would eliminate the therapeutic effects these drugs provide.

Rather than finding the motivation to combine the references in the prior art, the Examiner's rejection is a classic example of hindsight reconstruction in which the Examiner has selected features from several prior art references to create the subject matter claimed herein using applicant's specification as a "template". *Texas Instruments, Inc. v. U.S. Int'l. Trade Comm'n.*, 988 F.2d 1165, 26 USPQ 2d 1018 (Fed. Cir. 1993). It is a well-established principle of patent law that such hindsight reconstructions are improper. See, for example, *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 227 USPQ 523 (Fed. Cir. 1985); *In re Fine*, 837 F.2d 1071, 15 USPQ 2d 1596 (Fed. Cir. 1998).

Moreover, even if there was motivation to combine Barry with Shulze, and applicant believes there is not, applicant does not see how Shulze and Barry could be combined in the manner suggested by the Examiner. As pointed out above, the very purpose of Shulze is to provide a catheter having as small a diameter as possible. To do so, Shulze makes the various lumens in the catheter of specific shapes so as to fit closely to one another and provide the maximum fluid flow cross-section in a minimum overall catheter diameter. Schulze contemplates that the guidewire be movable proximally so as to expose an autoperfusion port 70 for the rapid passage of blood or other fluids through the guidewire lumen between port 70 and the distal end of the catheter. Barry, on the other hand, employs a guidewire having an enlarged abrasive tip for ablating deposits in the blood vessel. Such enlarged abrasive tip would not be capable of being withdrawn into the guidewire lumen, or would necessarily require the guidewire lumen to be enlarged so that the abrasive tip could be withdrawn through the catheter, all of which is repugnant to the express teachings of Shulze.

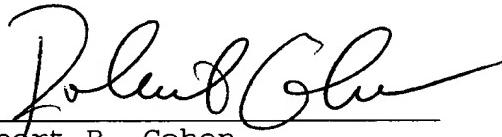
In view of the foregoing, it is respectfully submitted that claims 1, 10, 11 and 12 patentably distinguish over the combination of Shulze and Barry. Applicant therefore submits that claims 1, 10, 11 and 12, as well as the claims dependent therefrom, are in condition for immediate allowance, which action is respectfully requested.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited. If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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